

### REMARKS

Of claims 1-16 currently in this application, claims 1, 2, 5, and 15 have been cancelled and claims 3, 6, 7, 8, and 16 have been amended to more clearly define this invention. Reconsideration of this application in review of this response is respectfully requested.

The specification has been proofread for errors, and these have been corrected by rewriting the affected paragraphs.

The examiner has presumed that the subject matter of the various claims was commonly owned at the time that any inventions were made. This presumption is correct.

Claim 16 stands rejected under 35 USC § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 has been amended to clarify the relationship between the channel and orifices; thus, it is believed that this rejection has been overcome.

Claim 16 also stands rejected under 35 USC § 102 (e) as being anticipated by Kellogg et al. Kellogg et al. discloses the use of concentric rings around the exit port, as such textures have increased resistance to flow along the surface relative to smooth surface. Claim 16 calls for a plurality of orifices located in parallel in a channel, which orifices provide a higher static resistance than a single orifice but a substantially lower dynamic resistance to flow. This structure is not taught or shown within Kellogg et al., as this reference teaches a single orifice, along with concentric rings (which are not orifices). Thus, it is submitted that claim 16 is not anticipated by Kellogg et al. Also, as Kellogg et al. does not suggest the use of multiple parallel orifices, it is also submitted that Kellogg et al. does not render claim 16 obvious.

Claims 1-4 stand rejected under 35 USC § 103 (a) as being unpatentable over Lipshutz et al. in view of Parsons et al., as it would be obvious to use an absorbent as fluid driving means, and also to allow for fluid control without external means providing the control. This rejection is respectfully traversed.

Amended claim 3, which is original claim 3 rewritten as an independent claim containing the limitations of claims 1 and 2 (which claims have been cancelled), requires that the absorbent material is shaped such that the flow speed of said moving fluid front across said material is controlled by the shape of said material. The examiner states that Parsons shows a triangular shaped area which is used to help draw fluid through the device. The applicants respectfully disagree with this statement.

Parsons does teach an absorbent member to draw fluid through a channel, and also teaches a triangular shaped area which is located before the absorbent material. In this manner, the absorbent material does not have any effect on the driving force; the shape of the channel controls the speed before the fluid reaches the material. The device of Parsons also changes other characteristics of microfluidic flow, as the channel size is changed.

The present device uses an absorbent pad connected to the outlet of the microfluidic channel. By changing the shape of the material, it can act like a programmed pump which can vary the flow speed through the channel into any desired configuration, without affecting any microfluidic properties. Nowhere in the Parsons reference is this either taught or suggested. Thus, it is believed that claim 3 is not obvious in view of the Parsons reference, either combined with Lipshutz or any other reference of record.

Claim 4 calls for a specific shape of the absorbent material (triangular). It is submitted that this claim is not obvious in light of the prior art, for the same reasons as claim 3.

Claims 5-12 stand rejected under 35 USC § 103 (a) as being unpatentable over Yager et al. in view of Lipshutz et al. Claim 5 has been cancelled, while claim 6 has been amended to more correctly specify its use. Amended claim 6 now calls for a device for providing a continuous flow within a microfluidic channel when using gravitational force as a driving source, where a first passageway couples a first channel to a reservoir at a position between the top surface and bottom surface of the reservoir. With this construction, fluid entering the reservoir from the passageway will run down the sidewall of the reservoir when it enters, insuring that the flow into the reservoir will be a

smooth, continuous stream. This structure is neither taught nor suggested in the Yager or Lipshutz references. This claimed structure avoids pressure oscillations within the channel that would cause drops to form at the entrance to the reservoir, which would fall into the reservoir, causing an uneven, pulsating flow.

Claim 7 has been amended to correct some inaccuracies in its wording. Amended claim 7 now requires a microfluidic detection channel, an indicator channel, a sample channel, a first fluid, a second fluid, and indicating means. The Yager et al. reference does not teach an indicating means to which the diffusion pattern within the diffusion channel may be compared to determine concentration of the second fluid within said channel. As described on page 20, lines 8-18, "a chart 12 is placed near T-sensor 12e which contains indicia representative of different concentrations of the desired analyte," and "quantitation is achieved by interpreting the point at which a visible reaction has occurred at the interface between the sample and the indicator." Yager does teach viewports for viewing the flow channel at different points with a fluorescence microscope or with a photo detector. But there is no teaching nor suggestion of the use of indicating means containing indicia of different concentrations which can be read easily off of the chart.

Claim 8 has been amended to correctly indicate that the diffusion is in the detection channel. It is believed that the Yager reference does not teach or suggest, taken either alone or with any of the other cited references, a template which is placed over the detection channel having windows through which a visible reaction can be compared to an indicating means to determine concentration. Thus, it is believed that amended claim 8 is patentable over the references of record.

Claim 9 describes a microfluidic device having a structure in which fluid from one channel entering a main microfluidic channel cannot form a drop which will block fluid entering the main channel from a second channel. This structure eliminates the formation of air bubbles in the main microfluidic channel. There is no teaching or suggestion in Yager or Lipshutz of this particular structure. Claim 10 limits the structure of claim 9 by defining the size of the inlet channels; claim 11 further limits the structure by defining the size of the outlet channel openings; claim 12 further limits claim 9 by adding a first and second reservoir; and claims 13 and 14 limit claim 12 by defining the inlet openings as surface tension valves. It is submitted that neither Lipshutz nor Yager,

either taken together or combined with any other of the references of record, render claims 9-14 obvious.

Included with this Amendment is an Information Disclosure Statement along with several references. The examiner is respectfully to initial the Form, and return it with the next action.

Also enclosed is a Petition for a One Month Extension of Time. The Examiner is requested to charge Deposit Acct. No. 12-1677 for a fee of \$55, as this application is owned by a small entity. If the examiner requires proof of small entity status it will be provided. In addition, the fee for Submission of the Information Disclosure Statement (\$180) along with any other fee necessary, should also be charge to this account.

Finally, sheets showing a marked-up version of the changes to the Specification and the claims are included with this amendment.

For the reasons given above, it is believed that all claims now contained in this application are in condition for allowance, and such favorable action are respectfully requested.

Respectfully submitted,

hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on August 1, 2002.

Jerrold J. Litzinger  
Person Signing Certificate

Jerrold J. Litzinger  
Signature of Person Signing Certificate

August 1, 2002  
Date of Signature

Jerrold J. Litzinger  
Attorney for Applicants  
Reg. No. 29,402  
Sentron Medical, Inc.  
4445 Lake Forest Drive  
Suite 600  
Cincinnati, OH 45242

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION



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The paragraph beginning at page 16, line 10, has been amended as follows:

--FIG. 8 shows yet another version of the cartridge of the present invention.

Cartridge 10f contains a compressible pressure bubble 60 which is connected to ports [parts] 14a and 16a via passages 62, 64 respectively, while vent passage 50 connects reservoir 20 to atmosphere. T-Sensor 12 in cartridge 10f operates as follows: bubble 60 is depressed, forcing air through passages 62, 64, and consequently causing reagent in port 14a and specimen in port 16a to enter T-Sensor 12 via channels 14, 16 and 18 and into reservoir 20.--

The paragraph beginning at page 17, line 16, has been amended as follows:

--Referring now to FIG. 9, the operation of cartridge 10g will now be described. A sample, such as whole blood, is inserted into pressure head 40, while an acceptor reagent, such as water or saline is inserted into pressure head 42. Two parallel laminar streams will flow through channel 72 as the liquids travel [ravel] from channels 14, 16. Smaller components of the sample stream will diffuse into the acceptor stream. The two parallel flows are then split up into separate reservoirs 74, 76 at the end of H-Filter 70. Reservoir 74 will then contain a sample solution with a reduced concentration of the extracted component, while reservoir 76 contains the acceptor reagent containing the extracted reagent at a level of some fraction of its original concentration in the sample. The contents of both reservoirs 74, 76 can then be harvested from cartridge 10g for future use, or be processed through further integrated microfluidic structures.--

The paragraph beginning at page 19, line 15, has been amended as follows:

A simple detection method for analyzing the results of an assay performed [is] in a microfluidic format according to the present invention is shown in FIGS. 15-17. Referring now to FIG. 15, a basic T-Sensor device 12 is shown having an indicator port 14a and an analyte port 16a. Port 14a is connected to main channel 18 by a sample channel 14, while port 16a is connected to channel 18 by an analyte channel [16a] 16.

In FIG. 15, a high concentration analyte is loaded into port [16] 16a, and when T-Sensor 12 is operated with an indicator solution within port [14] 14a, a diffusion pattern forms as shown at 90. In FIG. 16, a low concentration analyte is loaded into port [16] 16a, and a different diffusion pattern 92 is generated.

The paragraph beginning at page 20, line 1, has been amended as follows:

--At some point along channel 18, the reaction between the analyte and indicator will become sufficiently intense to be seen visually. This point in channel 18, which is located some distance from channels [14a] 14 and [16a] 16, will correlate with a particular concentration of analyte within channel 18. Optical aids, such as a magnifying lens, colored filter layer, or slit may aid [on] in the manual visual interpretation of the concentration.--

The paragraph beginning at page 20, line 8, has been amended as follows:

--An example of a device for simple quantitation of a microfluidic device which requires no external instruments is shown in FIG. 17. Referring now to FIG. 17, a convoluted T-Sensor 12e having ports[14,16] 14a,16a and channels [14a, 16a] 14, 16 contains a main channel 18a upon which a viewing window 100 has been inserted. In addition, a chart 102 is placed near T-Sensor 12e which contains indicia representative of different concentrations of the desired analyte. During operation of T-Sensor 12e, quantitation is achieved by interpreting the point at which visible reaction has occurred at the interface between the sample and indicator. The only portion of [Channel 18] channel 18a visible is seen through viewing window 100. In this embodiment, the analyte may be at a 4+ to 5+ amount (1+ being low, 10+ being high) because in the 6+ view area of window 100, there is barely an reaction visible.--

#### IN THE CLAIMS

Claims 1 and 2 has been cancelled.

Claim 3 has been amended as follows:

3 (Once amended). A [The] device [ of claim 2, ] for moving fluids through a microfluidic channel, comprising:

a microfluidic channel having an inlet and an outlet;

a fluid contained within said channel;

and an absorbent material coupled to said outlet of said channel,

whereby when said fluid within said channel initially contacts said absorbent material, a driving force is created which moves [moved] said fluid through said channel to said outlet, wherein said fluid creates a moving fluid front across said absorbent material as said fluid contacts said material and [wherein] said absorbent material is shaped such that the flow speed of said moving fluid front across said material is controlled by the shape of said material.

Claim 5 has been cancelled.

Claim 6 has been amended as follows:

6 (Once amended). A device for providing a continuous flow within a microfluidic channel when using gravitational force as a driving source, comprising:

a fluid reservoir having a top surface and a bottom surface, and vent means for relieving pressure within said reservoir;

a first microfluidic channel connected to said reservoir;

and a first passageway for coupling said first channel to said reservoir at a position between said top surface and said bottom surface,

wherein said first passageway is sized such that fluid entering said reservoir from said first channel flows in a smooth, continuous stream.

Claim 7 has been amended as follows:

7 (Once amended). A device for providing a visual indication of the concentration of an analyte in a microfluidic channel, comprising:

a microfluidic detection channel having an inlet and an outlet;

an indicator channel coupled to said detection channel at said inlet;

[an] a sample [indicator] channel coupled to said detection channel at said inlet [opposite] opposite said indicator channel;

a first fluid introduced through said indicator channel into said detection channel toward said outlet;

a second fluid introduced through said sample channel into said detection channel toward said outlet;

and indicating means, [representative] containing indicia of second fluid concentration within said detection channel, located in proximity to said detection channel,

wherein when said first and second fluids flow within said detection channel toward said outlet, a diffusion pattern is formed indicative of the concentration of said second fluid within said detection channel, such that the diffusion pattern may be compared to said indicating means to determine concentration within said detection channel.

Claim 8 has been amended as follows:

8 (Once amended). The device of claim 7, wherein said indicating means further includes a template having a plurality of viewing windows such that said diffusion pattern within said detection [indicator] channel visible within said windows may be compared to said indicating means to determine concentration within said channel.

Claim 15 has been cancelled.



Claim 16 has been amended as follows:

16 (Once amended). A device for providing static resistance to flow in a microfluidic system, comprising:

[an inlet channel;

an outlet channel;]

a microfluidic channel, having an inlet and an outlet;

and a plurality of orifices, each having essentially the same dimensions, located in parallel within said channel between said inlet and outlet [channels],

whereby said orifices provide a higher [high] static resistance than a single orifice but a substantially lower dynamic resistance to flow.